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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,718	04/02/2002	Ann M. Diederich	P50972	8264

20462 7590 08/15/2003

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EXAMINER

REYES, HECTOR M

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 08/15/2003

Y

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

10/030,718

Applicant(s)

DIEDERICH ET AL.

Examiner

Hector M Reyes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 to 19 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 7,8,17 and 18 is/are allowed.
- 6) ☒ Claim(s) 1-6,9-11,13,14,16 and 19 is/are rejected.
- 7) ☒ Claim(s) 12, 15 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____. | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Paper Entry

Examiner acknowledges the following Papers:

- PCT/EO/905 form, filed on March 12, 2002 As paper no. 2
- Declaration, filed on April 2002, as Paper no. 3
- PCT/EO/DO/903 form, filed on April 19, 2002, as Paper no. 4
- Preliminary Amendment, filed on April 2, 2002 as Paper no. 5.

Status of The Claims

Claims 4, 5, 6, 9, 12, 15 and 19 had been amended. Currently claims 1 to 19 are under Examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 through 6; 9 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite and confusing because although it is drawn to a process wherein compounds embraced by formula (I) are prepared by the decarboxylation of compounds embraced by formula (A), some of the compounds wherein R" and R' are carboxylic acids or esters are indeed the same compounds in formulas (A) and (I) and therefore no transformation had occurred in the said process. Indeed both carboxylic acid or ester functionalities are present in what is described as the product as well as in the starting

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material. A chemical process requires a sequence of steps wherein a given bond breaking and/or bond forming takes places. There cannot be a process wherein the starting materials and the products are the same compounds. If a decarboxylation has occurred in compounds of formula (A), how it is possible that in the product (I), R' and R" can be carboxylic acid or esters?

Claim 1 is indefinite because the general conditions to carry out the said decarboxylation are not indicated. What are the general conditions wherein the said decarboxylation takes place? Is it a pyrolysis process? Is the hydrolysis of the ester groups required? If so, is it carry out in acid media or in basic media?

Claim 2 recites the limitations "the process of claim 1, wherein the diester or diacid is combined with about 1 equivalent of a base, about 3 equivalent of water and about 3 equivalent of an alkali salt in a suitable solvent". There is insufficient antecedent basis for these limitations in the claim. Process outline in claim 1 does not required any of the said elements.

Claim 3 recites the limitations "the process of claim 1, whereinthe base is pyridine and the salt is lithium chloride". There is insufficient antecedent basis for these limitations in the claim. Process outlined in claim 1 does not require a base or a salt.

In claims 4, 5 and 6, the phrase "The process of any one of claims 1". Such phrase is indefinite, *unless evidence is provided wherein it is shown that claim 1 indeed comprises more than one claim.*

In claim 4, the phrase "one group is substituted on at the 3 position and the other group is substituted on the 4 position" is indefinite. What are the substituents of the said group

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R? Is the said position a position on the R group or is a position of the benzene ring described in formula (A) or in the benzene ring of formula (I)?

In claim 9, the phrase "A compound according to any one of the claims 7" is indefinite, *unless Applicants shows that there are more than one claim in said claim 7.*

In Claim 19, the phrase "a compound according to claim 17" is indefinite because Claim 17 is not drawn to Compounds if not that it is drawn to a process.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 10, 11, 13, 14 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Dei et al, Journal of Medicinal Chemistry, 1991, 34(7). Pages 2219-2225. Dei discloses the preparation of verapamil analogues with restricted flexibility. As synthetic intermediates, Dei prepared:

- Benzeneacetonitrile alpha, alpha-bis(2-hydroxyethyl)-3,4-dimethoxy, see compound 22, page 2220 and derivative 25, page 2221.
- Benzeneacetonitrile, alpha, alpha –bis[ethenyloxy)ethyl]-3,4,dimethoxy, see compound 20, page 2220.
- Benzeneacetonitrile, alpha, alpha-bis(2-chloroethy)-3,4-dimethoxy, see compound 26, page 2220.

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- Regarding the process for the preparation of compound 20, see Scheme III, page 2220 and Experimental Section.

Allowable Subject Matter

Compounds embraced by claims 7 and 8 were not found disclosed in the prior art.

And are presumed allowable. Process for the preparation of the said compounds is also presumable allowable subject matter.

Claims Objections

Claims 12 and 15 are objected because the said claims depend, directly or indirectly on rejected claims.

CONCLUSION

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Christensen, IV US patents:

- 5552438
- 5602157
- 5614540
- 5643946

Wherein a series of esters of cyclohexanecarboxylic acid bearing a phenyl ring and a cyano group at the four position of said cyclohexane are disclose.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hector M Reyes whose telephone number is (703) 605-1153. The examiner can normally be reached on M-F 9 to 4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Alan Rotman can be reached on (703) 308-4698. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 or (for regular communications and (703) 308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Héctor M. Reyes, Ph D JD

August 12, 2003


ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600